



# **Annex 1**

## **Second Post Implementation Review of The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPC 2013)**

### **Evidence Review**

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## Summary

This is the second Post Implementation Review (PIR) for The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPC 2013). The duties under BPC 2013 were evolutions of long-standing and well-understood duties under previous legislation, with the change being one of refinement, collation and simplification. The first PIR found no evidence to suggest that the original IA assumptions were not still relevant and there were no significant lessons or changes or areas for simplification identified by the review.

Based on what was assessed by the first PIR in August 2018<sup>1</sup>, it was agreed by HSE's Evaluation Working Group that the second PIR would focus on issues highlighted via HSE's on-going work with the BPC 2013 regulations. Therefore, the scope and scale of the evidential needs of this second PIR were agreed to warrant a 'light-touch' and low resource approach in line with Magenta Book Supplementary Guidance for Conducting Regulatory Post Implementation Reviews (PIR)<sup>2</sup>.

The main sources of evidence which informed the post-implementation review were operational data and Chemicals Regulation Directorate feedback, and stakeholder intelligence. A short survey was circulated to Trading Standards Officers and Environmental Health Officers working for appointed authorities (Local Authorities) via an existing communications system, however, this yielded only one completed response.

Based on the [better regulation principles](#), the evidence suggests that the regulations are generally working well though suggestions for provision of an Enforcement Notice for biocides indicate that there is scope to explore opportunities to improve enforcement tools in more depth. The majority view was that the aims of the regulations could not be achieved with a system that imposed less burden on business.

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<sup>1</sup> [https://www.legislation.gov.uk/uksi/2013/1506/pdfs/uksiod\\_20131506\\_en.pdf](https://www.legislation.gov.uk/uksi/2013/1506/pdfs/uksiod_20131506_en.pdf)

<sup>2</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/879444/Magenta\\_Book\\_supplementary\\_guide\\_Guidance\\_for\\_Conducting\\_Regulatory\\_Post\\_Implementation\\_Reviews.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879444/Magenta_Book_supplementary_guide_Guidance_for_Conducting_Regulatory_Post_Implementation_Reviews.pdf)

## Introduction

1. This evidence review has been undertaken by the Health and Safety Executive (HSE) to accompany and support the second Post-Implementation Review (PIR) of The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPC 2013).
2. Following a recommendation in Professor Löfstedt's independent review of health and safety legislation (Nov 2011)<sup>3</sup>, the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013 (BPC 2013) reduce the number of legislative instruments and simplify domestic regulation. BPC 2013 does this in areas related to the protection of human health and the environment from risks associated with the supply, use and import/export of hazardous chemicals.
3. BPC 2013 formally appoints national authorities and provides for enforcement, including penalties for infringement, in respect of three direct-acting European Union (EU) Regulations, namely:
  - Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (to replace the Biocidal Products Directive 98/8/EC) (biocides);
  - Regulation (EU) No 649/2012 concerning the export and import of hazardous chemicals (a recast of Regulation (EC) 689/2008) (known as Prior Informed Consent [PIC]); and
  - Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP).
4. Due to the similarities between the three regimes, BPC 2013 replaced the existing domestic provisions which supported the EU Regulation on classification, labelling and packaging of substances and mixtures (CLP), and the EU Regulation concerning the export and import of hazardous chemicals (PIC) and combined them with provisions for the new Biocides Regulation.
5. The duties under BPC 2013 were therefore evolutions of long-standing and well-understood duties under previous legislation, with the change being one of refinement, collation and simplification.

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<sup>3</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/66790/lofstedt-report.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/66790/lofstedt-report.pdf)

## The First Post-Implementation Review

6. The first BPC 2013 PIR was undertaken in August 2018<sup>4</sup>, with the main conclusions being that:
- *“...the original impact assessment (IA) identified that the BPC Regulations impose minimal costs on businesses;*
  - *there is no evidence that the original IA assumptions are not still relevant and no intelligence of costs that the IA did not consider;*
  - *while [HSE] adopted a proportionate approach to the review, the evidence base is considered sufficiently robust;*
  - *there were no significant lessons or changes or areas for simplification identified by the review; and*
  - *no changes are needed to BPC as a result of this review”.*
7. The timing of the second BPC 2013 PIR is aligned to the review clause (s.38) in the legislation which states that the *“Secretary of State must from time to time carry out a review of regulations 5 to 33, set out the conclusions of the review in a report, and publish the report ...at intervals not exceeding five years”*. The second PIR therefore needs to be completed and delivered by 31<sup>st</sup> August 2023.

## Scope of the PIR

8. In line with Magenta Book Supplementary Guidance for Conducting Regulatory Post Implementation Reviews<sup>5</sup>, the evidential needs of the second BPC 2013 were assessed in terms of scope and scale, to ensure the work was appropriate and proportionate. ‘Scope’ refers to whether the PIR needs to look at the impact of the specific legislative changes or, alternatively, whether it should consider the appropriateness of the overarching legislative framework in which the changes sit (e.g., BPC 2013 vs. biocides regulation in general). Alongside this, ‘scale’ considers the wider importance of the PIR in terms of its political visibility, predicted economic impact, number of duty-holders it affects, etc. and therefore the level of resource which is required (high, medium or low).
9. In the case of BPC 2013, the scope was considered narrow as both the original impact assessment (IA)<sup>6</sup> and first PIR<sup>7</sup> were concerned with the changes due to the legislative consolidation recommended by Professor Löfstedt’s review. As for scale, a low resource ‘light touch’ level of evidence was considered proportionate and appropriate to support

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<sup>4</sup> [https://www.legislation.gov.uk/uksi/2013/1506/pdfs/ukiod\\_20131506\\_en.pdf](https://www.legislation.gov.uk/uksi/2013/1506/pdfs/ukiod_20131506_en.pdf)

<sup>5</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/879444/Magenta\\_Book\\_supplementary\\_guide\\_Guidance\\_for\\_Conducting\\_Regulatory\\_Post\\_Implementation\\_Reviews.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879444/Magenta_Book_supplementary_guide_Guidance_for_Conducting_Regulatory_Post_Implementation_Reviews.pdf)

<sup>6</sup> <https://www.legislation.gov.uk/uksi/2013/1506/impacts>

<sup>7</sup> [https://www.legislation.gov.uk/uksi/2013/1506/pdfs/ukiod\\_20131506\\_en.pdf](https://www.legislation.gov.uk/uksi/2013/1506/pdfs/ukiod_20131506_en.pdf)

the making of robust recommendations. This decision was based on the following considerations:

- The original BPC 2013 regulations were primarily administrative in aim and focus; there were no significant substantive policy changes.
- This is a second PIR, with the main policy objectives and economic impact having been previously assessed.
- The original impact assessment<sup>8</sup> indicated that the net cost to business per year (EANCB on 2009 prices) of BPC 2013 was £0. This is below the £5m *de minimis* threshold for review of the PIR by the Regulatory Policy Committee (RPC)<sup>9</sup>.

10. As part of the PIR planning process, HSE's Evaluation Working Group (EWG) assessed the scope and scale of the second BPC 2013. It agreed that it should be a low resource and 'light-touch' approach.

11. The low-resource approach means, in the interests of proportionality, that this 'second time around' PIR will only lightly touch on the objectives and economic impact of the BPC 2013 regulations as these requirements were previously assessed under the first PIR from August 2018<sup>10</sup>. This second review focused on issues highlighted via HSE's and relevant authorities' ongoing work with the BPC 2013 regulations.

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<sup>8</sup> [https://www.legislation.gov.uk/ukia/2013/45/pdfs/ukia\\_20130045\\_en.pdf](https://www.legislation.gov.uk/ukia/2013/45/pdfs/ukia_20130045_en.pdf)

<sup>9</sup> <https://www.gov.uk/government/organisations/regulatory-policy-committee>

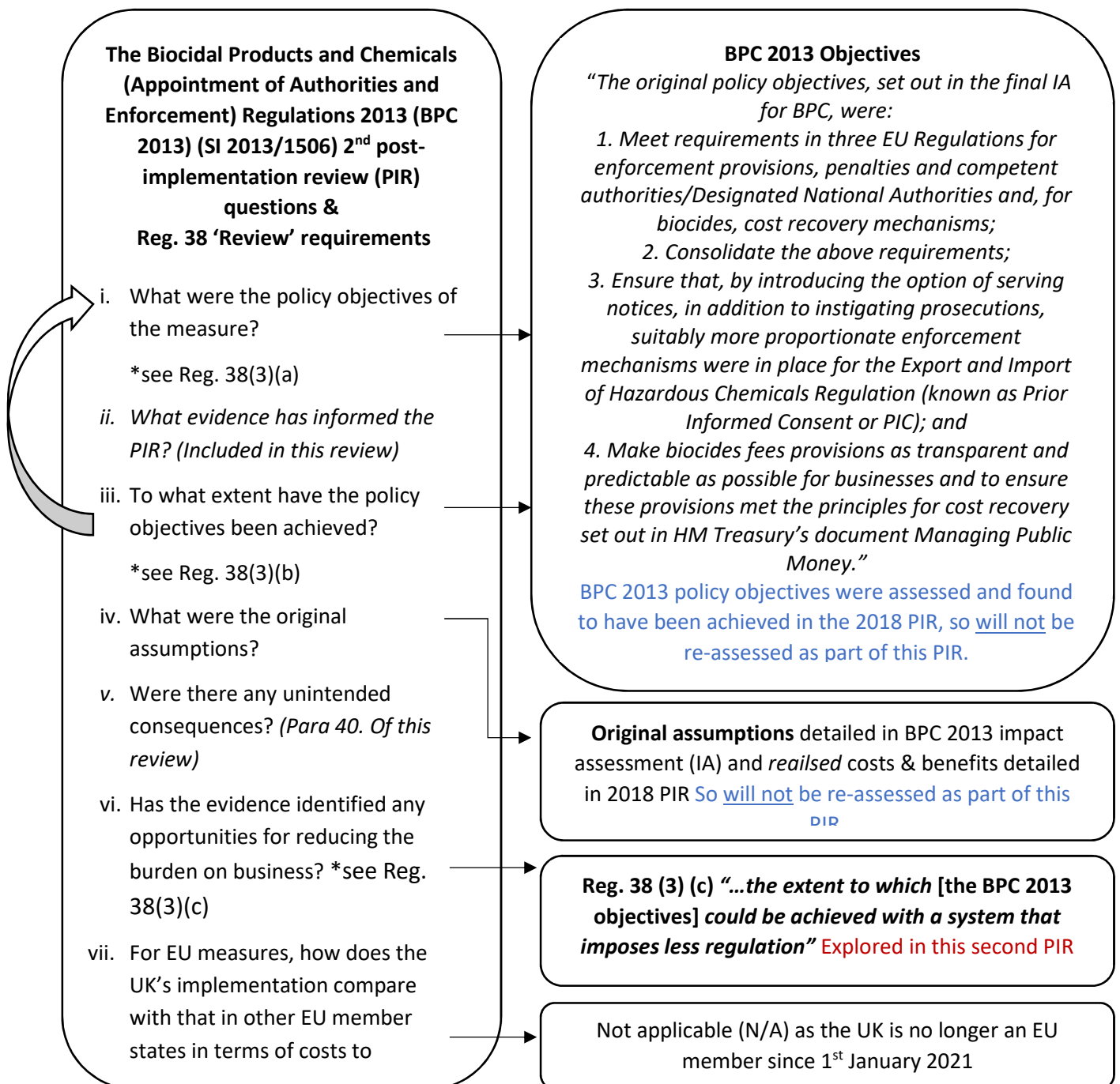
<sup>10</sup> [https://www.legislation.gov.uk/uksi/2013/1506/pdfs/uksi0d\\_20131506\\_en.pdf](https://www.legislation.gov.uk/uksi/2013/1506/pdfs/uksi0d_20131506_en.pdf)

## Post-Implementation Review (PIR) questions: Methods and Findings

### Evidence review structure

12. The structure of the Evidence Review is detailed in Diagram 1 (below), with the numbered sections directly mapping onto headings within this main document (e.g., ‘i. What were the policy objectives ...’ in the diagram equates to the ‘i. What were the policy objectives ...’ headed section in the main document).

Diagram 1: Structure of second BPC 2013 PIR evidence review



### Post-Implementation Review (PIR) questions

13. As per HM Treasury’s Magenta Book supplementary guide<sup>11</sup> and the Government’s business regulation guidance<sup>12</sup>, this PIR considers the legislative changes made by BPC 2013 in terms of the following overarching questions:

- i. What were the policy objectives of the measure?
- ii. What evidence has informed the PIR?
- iii. To what extent have the policy objectives been achieved?
- iv. What were the original assumptions?
- v. Were there any unintended consequences?
- vi. Has the evidence identified any opportunities for reducing the burden on business?
- vii. For EU measures, how does the UK’s implementation compare with that in other EU member states in terms of costs to business?

**i. What were the policy objectives of the measure?**

14. The previous BPC 2013 PIR<sup>13</sup> indicated that “[t]he original policy objectives, set out in the final impact assessment for BPC, were:

1. *Objective One: meet requirements in three EU Regulations for enforcement provisions, penalties and competent authorities/Designated National Authorities and, for biocides, cost recovery mechanisms;*
2. *Objective Two: consolidate the above requirements;*
3. *Objective Three: ensure that, by introducing the option of serving notices, in addition to instigating prosecutions, suitably more proportionate enforcement mechanisms were in place for the Export and Import of Hazardous Chemicals Regulation (known as Prior Informed Consent or PIC); and*
4. *Objective Four: make biocides fees provisions as transparent and predictable as possible for businesses and to ensure these provisions met the principles for cost recovery set out in HM Treasury’s document Managing Public Money.”*

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<sup>11</sup> Magenta Book 2020 (March 2020) - Supplementary Guide: Guidance for Conducting Regulatory Post Implementation Reviews ([https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/879444/Magenta\\_Book\\_supplementary\\_guide\\_Guidance\\_for\\_Conducting\\_Regulatory\\_Post\\_Implementation\\_Reviews.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/879444/Magenta_Book_supplementary_guide_Guidance_for_Conducting_Regulatory_Post_Implementation_Reviews.pdf))

<sup>12</sup> Business regulation: producing post-implementation reviews (<https://www.gov.uk/government/publications/business-regulation-producing-post-implementation-reviews>)

<sup>13</sup> Ibid 4



15. As detailed above, objectives one and two were fully met with the successful laying of the consolidated BPC 2013 regulations into UK law. Objective four is now covered under The Health and Safety and Nuclear (Fees) Regulations and is out of scope of this PIR.

16. The evidence review for this PIR therefore considered the following questions which addressed the objectives identified in the previous PIR:

- Have the enforcement provisions in BPC 2013 been effective?
- Have the additional enforcement mechanisms for PIC made a difference?
- Have there been any unintended consequences from BPC 2013?
- Are there any concerns or issues with the BPC 2013 regulations?

***ii. What evidence has informed the PIR?***

17. The evidence which has informed the second BPC 2013 PIR is detailed in this document, the 'Evidence Review'. It comes from several sources, including:

- HSE administrative and operational intelligence;
- HSE administrative and operational data, including enforcement action taken under BPC 2013;
- qualitative engagement with other BPC 2013 regulators via the REACH Enforcement Liaison Group (ELG); and,
- a survey of local authority (LAs).

18. The proposed research plan for BPC 2013 employed multiple approaches that were intelligence-led. This was assessed to be the most proportionate and appropriate method of investigating the issues and was approved by HSE's Evaluation Working Group (EWG). This approach follows engagement with the Regulatory Policy Committee (RPC) around the most recent Control of Asbestos Regulations 2012 (CAR 2012) PIR, where it was suggested that second time PIRs should focus on areas where there has been change and where the evidence was less robust. The general point was that HSE does not need to collect the same data again but should consider where data collection would be most beneficial. The proposed research approach for the second BPC 2013 PIR reflects this change in emphasis. Therefore, the objectives and economic model for BPC 2013, which were previously assessed under the 2018 PIR, have not been re-assessed under this second PIR. The focus has been on areas where there has been benefit in gathering further information on *specific* issues.

## Existing administrative and operational data and intelligence

19. Internal HSE operational intelligence and data were the initial focus of the evidence review. The PIR research team engaged with internal HSE colleagues, including the Chemical Regulation Division [CRD] enforcement team, to ask about how they were using the enforcement powers under BPC 2013, to get feedback from HSE’s internal policy knowledge, and to gather insights into day-to-day operational engagement with the legislation and operational data sources. Engagement with HSE Policy and Operations colleagues provided anecdotal evidence and operational data which described the practical operationalisation of these regulations, the fitness for purpose of these regulations and the appropriateness and proportionality of enforcement powers.

### 20. HSE Chemical Regulation Division (CRD) operational data:

Tables 1 to 3 that follow reflect HSE enforcement actions taken under BPC 2013. This includes the number of improvement notices (IMP) and prohibition notices (PRO) issued since 2013. (Source: HSE CRD enforcement database). An improvement notice directs a duty holder to correct a breach of the law whilst allowing that activity to continue; a date to comply will be set. A prohibition notice can only be used in respect of an activity that involves a risk of serious personal injury and will prohibit the continuation of that activity. There were no prosecutions under the BPC 2013 regulations during this time period.

*Table 1.* HSE enforcement of regulations concerning classification, labelling and packaging of substances and mixtures (CLP)

CLP											
2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
0	1 IMP 1 PRO	0	0	0	0	1 IMP	2 IMP	3 IMP	0	0	8

**Table 2.** HSE enforcement of regulation concerning the making available on the market and use of biocidal products (BPR)

BPR											
2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
0	0	0	0	0	1 IMP 1 PRO	0	0	4 IMP	2 IMP	0	8

**Table 3.** HSE enforcement of regulation concerning the export and import of hazardous chemicals (a recast of Regulation (EC) 689/2008) (known as Prior Informed Consent [PIC])

PIC											
2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
0	0	0	0	0	0	0	0	0	0	0	0

**21. Anecdotal evidence on the execution of powers:**

According to HSE CRD enforcement data, 821 biocides cases were closed between 2013 and 26 April 2023. While any type of enforcement notice might not have been appropriate, in some cases, it is known from operational experience that with provision of an Enforcement Notice for use in biocides cases, some of these cases may not have been closed without further action being taken. In these instances, it is likely that the dutyholder was not compliant with BPC 2013 but a risk of serious harm is not evident. Furthermore, a prohibition notice could be deemed inappropriate and disproportionate. It was felt that *‘provision of an enforcement notice (EN) for biocides (as provided for PIC) could improve the effectiveness of action taken relating to BPR considering the nature of prescriptive legislation and contextual factors which could impede timely and effective outcomes.’*

In parallel, *‘the provision of the option to serve an EN, in addition to instigating prosecutions, in relation to the Export and Import of Hazardous Chemicals Regulation (known as Prior Informed Consent or PIC) enables the prohibition of activity. Since 2013, the handful of PIC cases received were resolved without the execution of powers. Under different Regulations e.g., REACH, HSE’s Chemicals Regulation Division enforcement team has issued a much*

*greater number of ENs (compared to CLP and BPR) and have fed back that they are incredibly beneficial for chemical regulations.'*

## 22. Effectiveness of enforcement activity:

One of the primary messages coming out of these conversations was that there were no significant issues with BPC 2013, from HSE's point of view. Powers are proportionate and appropriate; however, the provision of an EN for biocides could streamline the enforcement process where risk of serious harm is not immediately evident. There was an agreement, however, that HSE is not the sole regulator using the enforcement powers under BPC 2013 and the research would need to engage other regulators to gather further evidence from elsewhere in the regulatory landscape.

## Engaging appointed authorities

23. Engaging with other BPC 2013 regulators had been challenging during the previous PIR<sup>14</sup>. For example, there were very low response rates from:

- BPC Competent Authorities (only three substantive responses from approximately 40 contacts);
- Local Authority (LA) Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs) (no responses from approximately 6,000 contacts on HSE's HELA Extranet mailing list);
- PIC enforcement agencies (three substantive responses from four contacts, including from HSE's CRD enforcement team); and,
- CLP enforcement partners (three substantive responses from 30 contacts, again including HSE's CRD enforcement team).

The PIR research team therefore spoke extensively to HSE colleagues about the best way of getting the views of other BPC 2013 regulators, mindful of the fact that the work was for a second PIR and had to be suitably proportionate in terms of its low / 'light-touch' scale.

## Targeting LA Environmental Health Officers and Trading standards Officers via HELEX email

24. Advice from HSE colleagues on how best to engage local authority regulators (e.g., EHOs and TSOs) was that the only feasible and proportionate option was to go through HSE's Local Authority Unit (LAU) and use the HELA Extranet mailing list. While the PIR research raised concerns about using the HELA Extranet (HELEX) option again after the low

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<sup>14</sup> [https://www.legislation.gov.uk/uksi/2013/1506/pdfs/uksiod\\_20131506\\_en.pdf](https://www.legislation.gov.uk/uksi/2013/1506/pdfs/uksiod_20131506_en.pdf)

response rate of the previous PIR, the point was made that the number of contacts had been recently been purged of inactive users to comply with GDPR<sup>15</sup> requirements. The ‘new’ list of approximately 1,600 contacts was seen to be more active and engaged. It was hoped that this would ensure that the BPC 2013 survey would go to a more receptive audience group.

25. As the most up to date in-use contacts list, using the HELA Extranet was preferable to an alternative sample-frame and approach, e.g., highly recourse intensive phone calls. The sample would have had to have included stratified groups due to variances in specialisms and areas covered by LAs; it would have had to have been randomised and have achieved a much greater response for any statistical calculations to be applied. Due to the light-touch nature of this second PIR, this sampling approach would have been disproportionate, and highly likely to have been unachievable based on the previous PIR engagement attempts and response rates.
26. Feedback from HSE colleagues helped to shape a short, targeted survey for designated authorities aimed at Environmental Health Officers (EHOs) and Trading Standards Officers (TSOs) in Local Authorities (LAs). The survey was kept short, minimised respondent burden as much as possible and encouraged consultation with colleagues. This increased the possibility of snowball sampling/engagement via explicit suggestions and provision for respondents to gather colleagues’ views. Despite these mitigations, HSE Local Authority Unit intelligence was that they were not aware of any issues with BPC 2013 from a LA perspective and, if this was true across EHOs and TSOs in LAs, the survey may not elicit responses, as people may simply not have any comments to provide.
27. With agreement from HSE’s Local Authority Team, an email invitation to complete the survey was sent to the updated HELEX mailing list on 20 March 2023. The short covering e-mail invited Environmental Health Officers (EHOs) and Trading Standards Officers – who regulate using BPC 2013 – to complete a short survey via the Qualtrics online survey platform. The full questions-set is included in Appendix 1. The survey facilitated free-text responses to collect views and experiences on implementing the regulations and to keep the survey length as short as possible in the absence of any known anecdotal issues which could shape questions with multiple choices, for example. It was designed to be simple and quick to complete to maximise participation, with an estimated completion time of between 10-15 minutes per response (depending on respondents’ experiences, and detail provided in free-text responses).
28. A survey deadline was set for two weeks after the initial e-mail was sent. Due to the extremely low number of initial responses (four) - all of which were incomplete surveys -

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<sup>15</sup> General Data Protection Regulation (GDPR)

a follow-up communication was sent, and the survey deadline was extended until 10 April 2023. The survey was formally closed on the system on 18 April. Given the lack of anecdotal evidence of issues experienced by LAs around BPC 2013, it was felt that this survey response window was ample and proportionate to engage respondents and allow time for completion.

29. The survey received one completed response and three incomplete responses. While the low response rate was disappointing, it was a similar response to a survey which was run for the previous PIR; that survey of LAs “attracted no responses”. The reason for the lack of interest and engagement with both PIR surveys is unclear; it may, however, be because local authority regulators don’t have anything they want to say about BPC 2013 (for better or worse). This ‘lack of issues’ conclusion is supported by the intelligence and feedback provided by HSE enforcement colleagues and other regulators (via the ELG).

30. The results from the LA survey undertaken via HELEX are detailed in table 4. below.

Table 4: Summary of responses to LA survey of EHOs and TSOs about BPC 2013

Respondent No.	What type of Local Authority do you work for?	What is your job role?	Approximately how many enforcement actions under BPC 2013 has the Local Authority you work for taken? Please provide brief details.		Do you think the BPC 2013 regulations are clear enough for you to conduct relevant enforcement actions effectively?	Are your enforcement powers adequate?	To your knowledge, are there any concerns or issues your organisation has with the BPC 2013 regulations?	To your knowledge, have there been any devolution consequences resulting from the BPC 2013 regulations?	To your knowledge, have there been any other unintended consequences resulting from the BPC 2013 regulations?	Are there any other impacts you think the Health and Safety Executive should consider in its review of the BPC 2013 regulations?
			BPR enforcement actions	CLP enforcement actions						
1.	Unitary Authority	Environmental Health Officer	-	-	-	-	-	-	-	-
2.	County Council	Trading Standards Officer	-	-	-	-	-	-	-	-
3.	Unitary Authority	eho	-	-	-	-	-	-	-	-
4.	Unitary Authority	Environmental Health Officer	0	0	May or may not	Unsure	Unsure	Unsure	Unsure	Unsure

## **Targeting other enforcing authorities via the UK Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (UK REACH) Enforcement Liaison Group (ELG)**

31. On advice of HSE colleagues, the PIR research team engaged non-local authority regulators through the REACH<sup>16</sup> Enforcement Liaison Group (ELG)<sup>17</sup>. This forum was suggested as it is a body made up of several regulators who use BPC 2013, including HSE as an enforcement agency under REACH and BPC 2013. It is an existing network and provided a low resource but robust information source which was proportionate to the scale and scope of this second PIR. Other ELG members who enforce using BPC 2013 include:

- The Environment Agency (EA)
- Natural Resources Wales
- Scottish Environment Protection Agency (SEPA)
- Office for Nuclear Regulation (ONR)
- Office of Rail and Road (ORR)
- Local Authority representatives

32. HSE social researchers attended an ELG meeting on 14 March 2023. They were allocated a 20-minute timeslot to pose focused questions and facilitate a guided discussion - much like a focus group with ELG members. This approach was an opportunistic, non-probability sampling method using an established stakeholder channel to reach as many enforcing body representatives as possible. We again increased the possibility of snowball sampling/engagement via explicit suggestions and provision for representatives to consult colleagues prior to the next ELG meeting, and after the meeting following out discussion.

Prior to the meeting the core questions of interest and a short briefing note were circulated to ELG members to prepare them for the discussion, to gather evidence and consult with colleagues. This helped to maximise the short time slot and focus the discussion. The core issues for discussion (presented on the slide in Appendix 2) were:

- Issues or concerns members had experienced with BPC 2013, if any;
- Any unintended consequences due to BPC 2013; and
- Enforcement action under BPC 2013.

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<sup>16</sup> Registration, evaluation, authorisation and restriction of chemicals (REACH)

<sup>17</sup> <https://www.hse.gov.uk/reach/authorities.htm>

33. Issues raised and discussed at the ELG meeting on Tuesday 14 March 2023:

<b>Issues with BPC 2013</b>		
<b>Scottish Environment Protection Agency (SEPA)</b>	Devolution consequences	Regulation 10(1)(ii) defines “justice” as meaning “in relation to Scotland, a sheriff, stipendiary magistrate or justice of the peace”. Stipendiary magistrates in Scotland were abolished in 2014.
<b>Enforcement action under BPC 2013</b>		
<b>Health and Safety Executive (HSE)</b>	Adequacy of BPR enforcement powers	<p>Provision of an enforcement notice (EN) for biocides (as provided for PIC) could improve the effectiveness of action taken relating to BPR considering the nature of prescriptive legislation and contextual factors which could impede timely and effective outcomes.</p> <p>HSE Inspectors do not have powers to pull products off the market.</p>
	Effectiveness of enforcement action taken under BPC2013	Another comment from ELG members was that without provision of powers to issue enforcement notices (EN) the effectiveness of enforcement action taken under BPC 2013 is somewhat limited. By way of example, during the COVID pandemic, HSE were investigating hand sanitisers, surface disinfectants etc. in relation to biocides and CLP. Where offending businesses were identified, HSE inspectors were limited to writing stern letters to these businesses rather than being able to issue an enforcement notice (EN). It has been reported by HSE CRD colleagues that hundreds of these letters were issued.
	Impacts on LA Trading Standards	HSE’s inability to issue ENs for biocides meant that TS had to have a more collaborative approach versus a regulatory one by necessity. In comparison, far more enforcement actions under



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(TS) of lack of EN for biocides	REACH have been recorded. Further to this issue, inspectors do not have powers to pull products off the market.
Cost recovery for enforcement work	For the BPC regs, made jointly under HSWA and European Communities Act, the decision was made not to engage in charging – BPC work is outside scope of Fee for Intervention [FFI]), so is not cost recoverable.

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### Limitations of the approach

34. As detailed above, the PIR research team were aware and cognisant of the difficulties around collecting information and data about the operation of BPC 2013 based on the experiences of the previous PIR. The research approach used was, however, considered proportionate given the necessary low / ‘light-touch’ scale of the PIR. To help increase response rates for the survey, it was both focused and kept short in length, as well as having a good amount of time for completion and there was a subsequent extension to said deadline. Furthermore, to mitigate for the possibility that survey respondents may not have all answers to hand or available to them at any point, mandatory response mechanisms were not used in the survey design. This had the advantage of allowing respondents to answer any questions they could at any point in the survey therefore reducing dropouts. Conversely, the risk that poor quality/unusable data was collected due to no question being mandatory meant that a number of respondents simply answered ‘unsure’ to many of the questions (although this can also be read as there being no material or significant issues to comment upon).
35. Overall, the hope was that intelligence from, and consultation with, internal HSE colleagues, engagement with BPC 2013 regulators via the REACH ELG, and responses received from the LA survey would provide sufficient evidence for the PIR. While the latter approaches yielded good information, the survey of LAs did not perform as hoped for with only limited data provided by one respondent who completed the whole survey (although it was marginally better than the “*attracted no responses*” result from previous PIR).
36. It is encouraging that the data we collected internally provides contextual and anecdotal evidence of BPC 2013 issues. Though the sample of appointed regulator contributors was self-selected and opportunistic, prior to engagement, contributors were asked to consult with colleagues in their organisation to widen out the opportunity to share evidence for this review. No prior evidence of issues with BPC 2013 had been raised with the regulator, either before or during this second PIR.

**iii. To what extent have the policy objectives been achieved?**

37. As described in the opening section of this PIR report – *i. What were the policy objectives of the measure?* - there have been no significant or notable changes to the appointment of authorities and/or enforcement around biocidal products and chemicals – e.g., BPC 2013 – since August 2018 when the last PIR was completed. As such the findings from previous PIR, in terms of whether the policy objectives have been achieved, and in the interests of proportionately and scale, have not been re-assessed for the current PIR. In summary, the BPC 2013 policy objectives were found to have been achieved (as detailed in the 2018 PIR), and the current PIR accepts that they are still appropriate and relevant.
38. The focus of the current PIR is on any issues or problems with the on-going operation of BPC 2013, with a particular emphasis on the enforcement aspects of the regulations. Overall, there have been few, if any, notable or significant issues highlighted in discussions with internal HSE colleagues and other BPC 2013 regulators including local authorities.

**iv. What were the original assumptions?**

39. The original assumptions for BPC 2013 are detailed in the related impact assessment (IA)<sup>18</sup>. This stated that the Equivalent Annual Net Costs to Business (EANCB) for the BPC 2013 changes was £0 (zero). As detailed previously, these assumptions were comprehensively considered within the 2018 PIR and will not be re-assessed within the current work; the previous PIR found that there was “*no evidence that the assumptions made in the original IA are not still relevant, and HSE has received no intelligence of additional costs that the IA did not consider*”. Furthermore, in terms of scale, the costs of BPC 2013 were well below the £5 million *de minimis* threshold required by the Regulatory Policy Committee (RPC). This made any re-assessment disproportionate and unnecessary.

**v. Were there any unintended consequences?**

40. After being in operation for nearly ten years, BPC 2013 is now very much the ‘norm’. It is therefore difficult to isolate consequences, intended or unintended, which the original BPC 2013 regulations caused. Furthermore, for many stakeholders and duty-holders, the original intentions behind the regulations are now very much in the past – e.g., meeting the requirements of three EU Regulations and consolidating these into a single set of regulations. As the previous PIR stated, for BPC 2013, there are “[n]o new duties ... proposed for businesses, ... hence minimal need for BPR, PIC or CLP legislation dutyholders to familiarise themselves with the proposed administrative arrangements in relation to enforcement, penalties and appointment of Competent Authorities/DNAs”.

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<sup>18</sup> <https://www.legislation.gov.uk/uksi/2013/1506/impacts>

41. Overall, there appear to be no notable unintended consequences related to the BPC 2013 regulations identified by stakeholders consulted as part of this work. This largely reflects the finding of the 2018 PIR which found that while *“there had been unintended effects of the biocides and CLP elements of the Regulations”* these *“... examples were almost exclusively related to the BPR, CLP and PIC regimes themselves rather than being related to the BPC Regulations”*.

***vi. Has the evidence identified any opportunities for reducing the burden on business?***

42. The focus of this PIR is on identifying any issues with the BPC 2013 regulations and suggesting possible improvements and ‘fixes’. This aim is intended to help improve the regulations and, in turn, provide opportunities to reduce the burden on business associated with BPC 2013. The lack of major issues raised throughout the research suggests that the BPC 2013 regulations are working relatively well. This echoes the findings from the previous PIR which identified a number of minor issues but concluded *“these are unlikely to warrant high priority in the near future, as there would typically need to be a risk of actual serious harm: the low level of actual enforcement suggests this is not the case”*. The updated enforcement figures in this PIR supports this view and where the provision of an Enforcement Notice for biocides has the potential to increase compliance with regulations where letters from HSE have not resulted in that desired outcome, there has not been a risk of serious personal harm as this would have been addressed by a prohibition notice. Any potential opportunities and benefits relating to this suggestion may be explored further at a later stage, for example, as part of considering potential regulatory reforms to Great Britain retained EU law under the Retained EU Law (Revocation and Reform) (REUL) Act 2023.

***vii. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements?***

43. Following the UK’s departure from the European Union (EU), there is no longer a requirement to have regard for how other Member States have implemented the relevant EU Directives. HSE assessed that it would be disproportionate to approach EU Member States or other countries outside the EU to gather this information as part of this post-implementation review. The feasibility of international comparisons of enforcement powers will be considered as part of any regulatory reform work under the REUL Act.

## CONCLUSION

44. Based on the evidence which has been collected, collated and analysed for the second BPC 2013 PIR, the following broad conclusions are supported:

- The objectives and original assumptions for BPC 2013 were assessed in the 2018 PIR and have not been re-assessed in this second PIR.
- The focus of this second PIR has been to identify any potential issues with the BPC 2013 regulations, with a focus on the use of the enforcing powers by UK regulators.
- This approach was used in discussions with internal HSE colleagues, other BPC 2013 regulators and via a survey to local authority Trading Standards Officers and Environmental Health Officers.
- No significant issues or problems with BPC 2013 were raised which flagged serious concerns. The primary evidence collection, and secondary analysis of enforcement data showed low levels of BPC 2013 dutyholder infraction and where risk of serious harm was identified, provision for prohibition notices was available to use. However, evidence indicates that there could be further scope to explore the provision of an enforcement notice for biocides enforcement in more depth. While it would be possible to reach estimates for the proportion of cases which might otherwise have received an enforcement notice if provision were there, a robust dataset could be generated over a specified period to provide robust proportions and quantifiable estimates to supplement retrospective historical data proportion estimates. This could then inform a decision on the benefits and proportionality of such a provision.
- Overall, it therefore appears that the BPC 2013 regulations are operating effectively with scope to enhance a specific enforcement tool for biocides enforcement. It may be beneficial to review available data after an agreed period to inform a policy review.

## Appendix 1: Local Authority EHO and TSO survey

# Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013

### Why are you receiving this short survey?

This survey provides an opportunity for Local Authority representatives to inform the second Post Implementation Review of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013.

The Health and Safety Executive (HSE) will assess the effectiveness of these Regulations and whether they achieved their policy aim. The BPC 2013 Regulations allocate enforcement responsibility to Local Authorities for:

- Biocidal Products Regulation (BPR).
- Classification, Labelling and Packaging for substances and mixtures Regulation (CLP).

You can view the BPC 2013 regulations here:

<https://www.legislation.gov.uk/ukxi/2013/1506/contents/made>

Your contributions will help us to better understand how these regulations are being operationalised and/or are affecting operations in specific areas of enforcement. Depending on how much detail you provide, the survey could take as little as 10-15 minutes. Please feel free to consult with your colleagues and provide a collective response. **Alternatively, please forward this survey to colleagues if you personally are not in a position to provide information on this area of enforcement.**

**The survey will close at the end of the day on Monday 10 April 2023.**

### **This survey is completely voluntary**

Your participation is voluntary, it is not mandatory and you can withdraw at any time. You can withdraw all of your responses or specific responses at any time during the process.

### **Protecting your data**

You only need to provide your contact details if you want us to be able to contact you to discuss your response. We only ask for role details for analytical purposes. Unattributable comments may be published in the Post Implementation Report for the purposes of presenting evidence. Information from the survey is being collected for the purposes of this post implementation review only. HSE will not provide any of the data collected to unconnected parties. Data collected will be securely stored and will be deleted upon

completion of the post implementation review process. Any and all data is processed in line with HSE's privacy policy ([www.hse.gov.uk/privacy.htm](http://www.hse.gov.uk/privacy.htm)). No information you provide will be used for regulatory inspection purposes. Thank you for your help.

If you have any problems or questions, please contact Emma Arhire at [emma.arhire@hse.gov.uk](mailto:emma.arhire@hse.gov.uk)

What type of Local Authority do you work for?

- County council
- District council
- Unitary authority
- Metropolitan district
- London borough
- Shared services
- Other, please specify: \_\_\_\_\_

What is your job role?

\_\_\_\_\_

Approximately how many enforcement actions under BPC 2013 has the Local Authority you work for taken? *Please provide brief details.*

- BPR enforcement actions \_\_\_\_\_
- CLP enforcement actions \_\_\_\_\_

Do you think the BPC 2013 regulations are clear enough for you to conduct relevant enforcement actions effectively?

- Definitely not
- Probably not
- May or may not
- Probably yes
- Definitely yes

Are your enforcement powers adequate?

- Yes
  - Unsure
  - No (Please provide brief details)
-

To your knowledge, are there any concerns or issues your organisation has with the BPC 2013 regulations?

- No
  - Unsure
  - Yes (Please provide brief details)
- 

To your knowledge, have there been any **devolution** consequences resulting from the BPC 2013 regulations?

- No
  - Unsure
  - Yes (Please provide brief details)
- 

To your knowledge, have there been any other **unintended** consequences resulting from the BPC 2013 regulations?

- No
  - Unsure
  - Yes (Please provide brief details)
- 

Are there any other impacts you think the Health and Safety Executive should consider in its review of the BPC 2013 regulations?

- No
  - Unsure
  - Yes (Please provide details)
-



In some instances we may need to re-contact you to clarify your responses or ask further questions based on your responses. If you are happy to be re-contacted, can you please provide a name and work email address below. These details will be deleted on completion of the second BPC 2013 PIR.

Please provide your name (*optional*)

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Please provide your work email address (*optional*)

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## Appendix 2: Stimulus slide for Enforcement Liaison Group Meeting



### Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (2013): Post implementation review questions for enforcing authorities

#### Aim of discussion:

To get a view on any thoughts, issues, concerns or suggestions you may have in relation to three core areas.  
Starting with..

#### Issues with BPC 2013 regs, if any (5 min discussion)

- E.g.,
  - Lack of clarity?
  - Enforcement powers adequate?
  - Difficulties in applying the enforcement provisions?
  - Devolution consequences?

#### Unintended consequences, if any (5 min discussion)

- E.g.,
  - Have there been any unintended consequences from BPC 2013?
  - Unexpected costs for you and/or duty-holders?

#### Enforcement action under BPC 2013 (5 min discussion)

- E.g.,
  - What type of breaches have been enforced (CLP/PIC/biocides)?
  - Approximately how many enforcement actions have you taken?